REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated July 18, 2007 are respectfully requested. A Petition for three-month time extension accompanies this response with the requisite fee due of $1,020.00. Also enclosed is a Power of Attorney, Request for Change of Correspondence Address, a Petition under 37 C.F.R. §1.8(b)(1), and documents related to the correction of inventorship in the application.

I. Amendments

Claim 1 has been amended to include the limitations of originally filed claims 6, 7, 16, and 20.

Claim 10 has been amended to introduce antecedent basis for the N-terminal and C-terminal moiety terms.

No new matter has been added by these amendments to claim 1.

II. Objections and Informalities

The Examiner has objected to the Applicants' request to correct inventorship under 37 CFR 1.48(a) as lacking required supporting documents. Attached are A Petition to Correct Inventorship; Statements of Inventors Small and Rini filed earlier in this application, and an amended Application Data Sheet, as requested by the Examiner, to correct inventorship.

The Examiner has objected to the Sequence Listing submitted in the application, since it names now-removed inventors Small and Rini. Also enclosed is an amended Sequence Listing, diskette and matching declaration.

The Examiner has objected to the specification in the application, as containing various formalities, including the designation of trademarked items, and the inclusion of the attorney docket number on each page of the specification. The specification has been amended to delete the attorney docket number. Appropriate corrections have been made to the specification.

The Examiner objected to claim 5 as drawn to non-elected species of cancer. By this amendment claims 5 and 6 have been cancelled, and the limitations of claim 6 included in amended claim 1.

III. Rejections under 35 U.S.C. §112, second paragraph

Claim 2 was rejected under 35 U.S.C. §112, second paragraph for lacking definiteness as to the meaning of "tumor-specific antigen."

By this amendment, claim 2 and the terms "tumor-specific antigen" and "tumor-associated antigen" have been cancelled and removed, respectively. It is therefore respectfully requested that rejection be withdrawn.

IV. Rejections under 35 U.S.C. §112, first paragraph

Claims 13-15 and 17-19 were rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement, and in particular, for failing to disclose peptides that have a specified degree of homology (at least 70%, at least 80%, or at least 90%) with either SEQ ID NO: 1 (huPAP) or SEQ ID NO: 3 (huGM-CSF).

While not conceding that the scope of the claimed invention should be so limited under the written description requirement of 35 U.S.C. §112, first paragraph, the Applicants submit that the amendment to the claims to cancel claims 13-15 and 17-19 is effective to overcome this rejection.

V. Rejections under 35 U.S.C. §112, first paragraph

Claims 1-15 and 17-19 were rejected under 35 U.S.C. §112, first paragraph for failing to enable one skilled in the art how to make and use an immunotherapeutic composition other than one comprising APCs from a prostate cancer patient and stimulated ex vivo by a fusion protein comprising a PAP/GM-CSF fusion protein where PAP comprises SEQ ID NO: 1 and GM-CSF comprises SEQ ID NO:3.

While not conceding that the scope of the claimed invention should be so limited under the enablement requirement of 35 U.S.C. §112, first paragraph, the Applicants

submit that the inclusion of the above limitations into amended claim 1 is effective to overcome this limitation.

VI. Rejection under 35 U.S.C § 102(b)

Claims 1-12, 16, and 20 were rejected under 35 35 U.S.C § 102(b) an anticipated

by Small et al. Claims 1-12 were rejected under 35 35 U.S.C § 102(b) an anticipated by Burch et al. These rejection are respectfully traversed in view of the foregoing amendment to claim 1, and the following remarks.

A. The standard for of anticipation

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

B. The Claimed Claims

The present invention, as embodied in amended claim 1, is directed to an immunotherapeutic composition that consists essentially of

(a) activated, isolated antigen presenting cells (APCs) that are obtained from a patient diagnosed with prostate cancer having a moderate to well differentiated cancer grade and a Gleason score of 7 or less

(b) where the APCs are stimulated by exposure ex vivo to a fusion protein composed of human prostatic acid phosphatase (huPAP) having the sequence identified by SEQ ID NO:1 linked at its C terminus via a linker peptide to the N-terminus of human granulocyte-macrophage colony stimulating factor (huGM-CSF) having the sequence identified by SEQ ID. NO: 3.

The claimed invention is based on the discovery that an optimal response to immunotherapy using activated APCs to treat prostate cancer is achieved when the APCs are obtained from a prostate-cancer patient having a moderate to well

differentiated cancer grade and a Gleason score of 7 or less, as detailed in the methods described in Examples 3 and 4 of the specification.

C. The Small *et al.* reference

Small *et al.* describe studies involving a total of 31 prostate cancer patients who are treated with immunotherapy involving APCs activated with a PAP/GM-CSF fusion protein.

Nowhere does the Small et al. reference mention the Gleason score of the patients enrolled in the study, nor is there any evidence that any of the patients were Gleason 7 or less. In the absence of such a teaching, the Small et al. reference cannot be said to anticipate the presently claimed invention, either expressly or inherently.

D. The Burch et al. reference

Burch et al. describe studies involving a total of 13 prostate cancer patients who are treated with immunotherapy involving APCs activated with a PAP/GM-CSF fusion protein.

Nowhere does the Burch et al. reference mention the Gleason score of the patients enrolled in the study, nor is there any evidence that any of the patients were Gleason 7 or less. In the absence of such a teaching, the Burch et al. reference cannot be said to anticipate the presently claimed invention, either expressly or inherently.

The Applicants therefore request that the rejection of the claims as anticipated by Small et al. or Burch et al. be withdrawn.

VII. Rejections under 35 U.S.C. §103(a)

Claims 1-12 16, and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Laus et al. (USPN 6,210,662) in view of Small et al. Claims 1-12, 16, and 20 were further rejected under 35 U.S.C. §103(a) as being unpatentable over Fikes

et al. (US2004/0037843) in view of Small et al. These rejections are respectfully traversed in view of the foregoing claim amendments and following remarks

A. The Present Claims

The presently claimed invention is discussed in Section VI above.

B. The Cited Art

Laus *et al.* discloses a therapeutic composition composed of APC derived from prostate cancer patients, and activated with a PAP/GM-CSF fusion protein. The reference doesn't show or suggest forming the composition using APCs from a prostate-cancer patient having a moderate to well differentiated cancer grade and a Gleason score of 7 or less.

Fikes *et al.* is discloses compositions for inducing epitope-based vaccines directed against tumor-associated antigens, including PAP, and including peptide-pulsed antigen-presenting cells. Nowhere does the Fikes et al. reference show or suggest forming a vaccine composition using APCs from a prostate-cancer patient having a moderate to well differentiated cancer grade and a Gleason score of 7 or less.

C. Analysis

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

* In the present case, the prior art does teach or suggest all of the claimed limitations, namely, a therapeutic composition for treating prostate cancer composed of APCs from prostate-cancer patients patient having a moderate to well differentiated cancer grade and a Gleason score of 7 or less. More generally, the

cited art does not provide any suggestion that optimal immunotherapy using activated APCs is achievable in cancer cells having a moderate to well differentiated cancer grade, and in the case of prostate cancer, a Gleason score of 7 or less. In the absence of any teaching in the cited art as to this feature, the prior art cannot be said to render the invention obvious.

Because the references, alone or in combination, fail to show or suggest all of the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for Allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4401.

Respectfully submitted,

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